

RANITIDINE 75- ranitidine tablet, coated
Major Pharmaceuticals

Major Pharmaceuticals Ranitidine 75 Drug Facts

Active ingredient (in each tablet)

Ranitidine 75 mg (as ranitidine hydrochloride 84 mg)

Purpose

Acid reducer

Uses

- relieves heartburn associated with acid indigestion and sour stomach
- prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain foods and beverages

Warnings

Allergy alert: Do not use if you are allergic to ranitidine or other acid reducers

Do not use

- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
- with other acid reducers

Ask a doctor before use if you have

- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with **lightheadedness, sweating or dizziness**
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent **chest pain**
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain

Stop use and ask a doctor if

- your heartburn continues or worsens
- you need to take this product for more than 14 days

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- adults and children 12 years and over:
- to **relieve** symptoms, swallow 1 tablet with a glass of water
- to **prevent** symptoms, swallow 1 tablet with a glass of water **30 to 60 minutes before** eating food or drinking beverages that cause heartburn
- can be used up to twice daily (do not take more than 2 tablets in 24 hours)
- do not chew tablet
- children under 12 years: ask a doctor

Other information

- do not use if printed foil under bottle cap is open or torn
- store at 20°-25° C (68°-77° F)
- avoid excessive heat or humidity
- this product is sodium and sugar free

Inactive ingredients

D&C yellow #10 aluminum lake, FD&C blue #2 aluminum lake, FD&C red #40 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, titanium dioxide, triacetin

Questions or comments?

1-800-719-9260

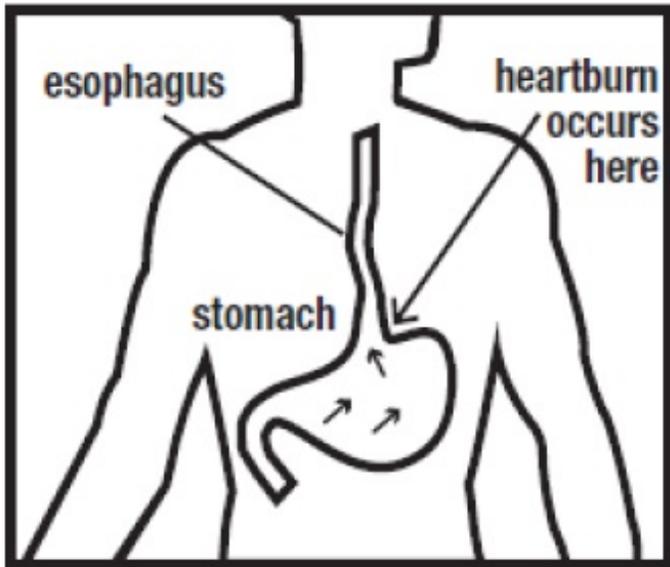
Consumer information

What you should know about Regular Strength Ranitidine Tablets, 75 mg Acid Reducer

(Please read all of this information before taking Ranitidine Tablets, 75 mg. Save this leaflet for future reference.)

What are Ranitidine Tablets, 75 mg?

- Ranitidine Tablets, 75 mg contain 75 mg of ranitidine (as ranitidine hydrochloride, 84 mg), a medicine that doctors have prescribed more than 200 million times worldwide.



Excellent Safety Record

- Ranitidine Tablets, 75 mg have been used safely and effectively for years as an over-the-counter medication.
- Ranitidine Tablets, 75 mg are sodium and sugar free.

What symptoms do Ranitidine Tablets, 75 mg relieve and prevent?

- Ranitidine Tablets, 75 mg relieve and prevent heartburn associated with acid indigestion and sour stomach.

Certain foods or beverages, and even lying down to sleep, can cause heartburn associated with acid indigestion or sour stomach. It is normal for the stomach to produce acid, especially after consuming food or beverages. However, acid in the wrong place, such as the esophagus, or too much acid, can cause burning pain and discomfort.

How should I take Ranitidine Tablets, 75 mg?

- To **relieve** symptoms, swallow 1 tablet with a glass of water.
- To **prevent** symptoms, swallow 1 tablet with a glass of water **30 to 60 minutes before** eating food or drinking beverages that cause heartburn.

This medicine can be used up to twice daily (do not take more than 2 tablets in 24 hours).

- Do not chew tablet

Ranitidine Tablets, 75 mg should not be given to children under 12 years old unless directed by a doctor.

- **Allergy alert:** Do not use if you are allergic to ranitidine or other acid reducers

How do Ranitidine Tablets, 75 mg work?

- Ranitidine Tablets, 75 mg reduce the production of stomach acid. This is what makes Ranitidine Tablets, 75 mg different from antacids, which neutralize the acid already in your stomach.

Antacids do not reduce the production of acid.

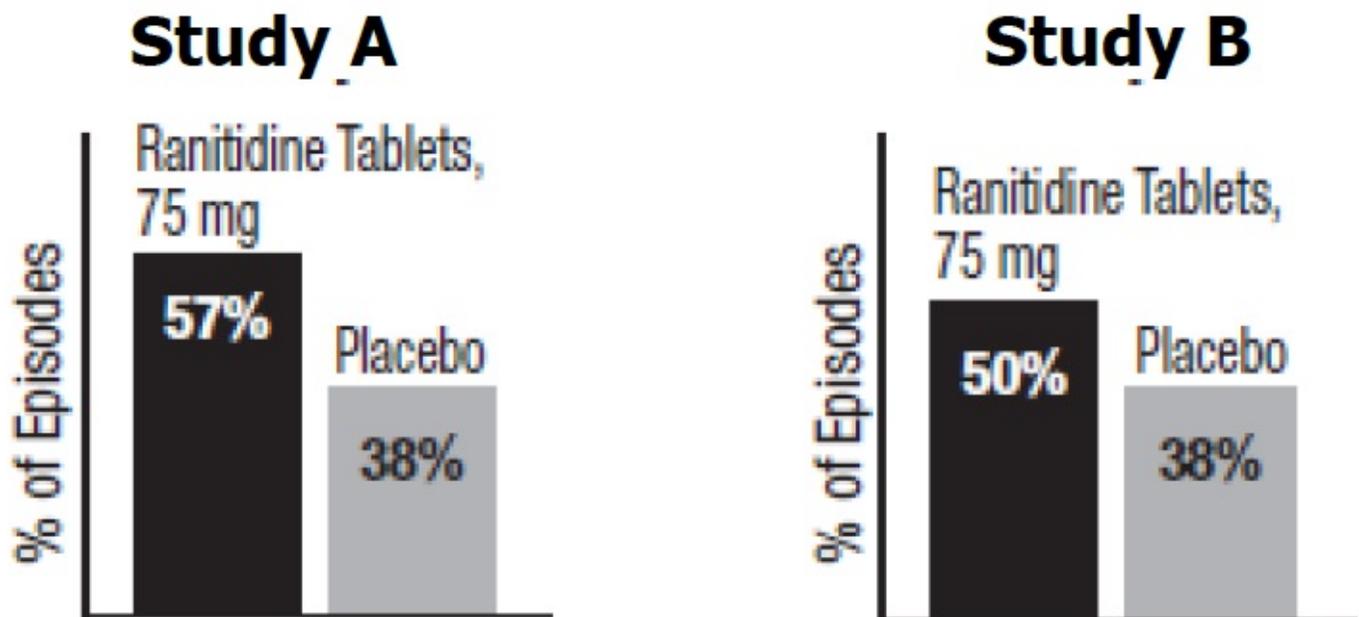
Additional tips for managing heartburn

- Do not lie flat or bend over soon after eating
- Do not eat late at night, or just before bedtime
- Certain foods or drinks are more likely to cause heartburn, such as rich, spicy, fatty, and fried foods, chocolate, caffeine, alcohol, even some fruits and vegetables
- Eat slowly and do not eat big meals
- If you are overweight, lose weight
- If you smoke, quit smoking
- Raise the head of your bed
- Wear loose fitting clothing around your stomach

Clinical studies prove Ranitidine Tablets, 75 mg are effective in relieving and preventing heartburn.

In clinical studies, Ranitidine Tablets, 75 mg were significantly better than placebo pills.

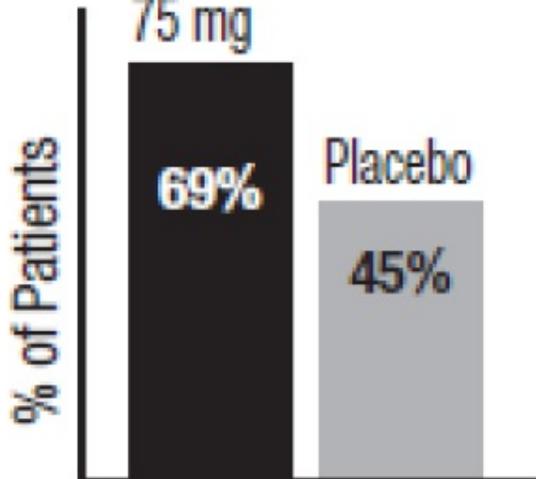
Percent of Heartburn Episodes Relieved



Percent of Patients with Prevention or Reduction of Heartburn Symptoms

Study C

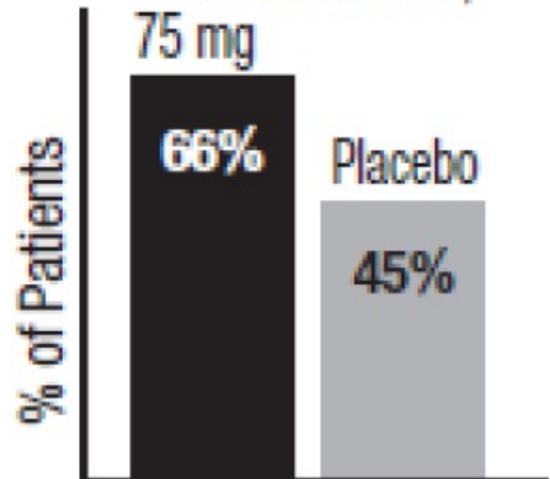
Ranitidine Tablets,
75 mg



Pill taken 60 minutes
before eating

Study D

Ranitidine Tablets,
75 mg



Pill taken 30 minutes
before eating

When should I see a doctor?

- **Do not use**
- if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.
- with other acid reducers
- **Ask a doctor before use if you have**
- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with **lightheadedness, sweating or dizziness**
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent **chest pain**
- frequent wheezing, particularly with heartburn
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- **Stop use and ask a doctor if**
- your heartburn continues or worsens
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If pregnant or breast-feeding,

ask a healthcare professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Questions {or comments}?

BOTTLES: Bottle is sealed with printed foil under cap. Do not use if printed foil is open or torn.

BLISTERS: Do not use if the individual blister unit is open or torn.

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Package/Label Principal Display Panel

REGULAR STRENGTH

RANITIDINE 75

Ranitidine Tablets USP, 75 mg

Acid Reducer

PREVENTS AND RELIEVES HEARTBURN associated with acid indigestion and sour stomach

COMPARE TO the active ingredient of ZANTAC® 75

Actual Size

30 Tablets (30 Doses)



RANITIDINE 75

ranitidine tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-6715
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
RANITIDINE HYDROCHLORIDE (UNII: BK76465IHM) (RANITIDINE - UNII:884KT10YB7)	RANITIDINE	75 mg

Inactive Ingredients

Ingredient Name	Strength
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	PINK	Score	no score
Shape	HEXAGON (6 sided)	Size	8mm
Flavor		Imprint Code	RT
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6715-46	1 in 1 CARTON	09/26/2018	
1		30 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:0904-6715-52	1 in 1 CARTON	09/26/2018	
2		60 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076195	09/26/2018	

Labeler - Major Pharmaceuticals (191427277)

Revised: 12/2019

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